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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,430	10/03/2003	William J. Wechter	3829.01-1	1619

7590 06/02/2005

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EXAMINER

DENTZ, BERNARD I

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/678,430

Applicant(s)

WECHTER ET AL.

Examiner

Bernard Dentz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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It is known that NSAIDS, which are carboxylic acids, and their esters have much utility as pharmaceuticals. In the past they were all used in the racemic or S-enantiomeric form. Lately the R-enantiomeric form has shown improved utility over the S-and consequently the racemic form in certain applications. See Wechter et al, Cancer Research article of record and Wechter et al, US Patent 5,981,592 which is now used in the rejections to replace the Wechter article. The article demonstrates that R-flurbiprofen inhibits the progression of prostate cancer in the TRAMP mouse. Zavitz, US 2003/0027867 A1 of record discloses the use of R-NSAIDs and their esters in the treatment of AIDS. It states at p. 1, col. 2 in par. [0009] that "unlike S-NSAIDs, which are known to be associated with various side effect, R-NSAIDs do not cause any significant adverse reactions." The thesis of the below rejections is that since esters of NSAIDS are known to be used for the same application as the parent carboxylic acid that, they are generally obvious over said parent.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al, US Patent 5,981,592 in view of Zavitz. The former teaches the benefits of R-NSAIDs in the treatment of cancer and AIDS. The esters thereof are commonly used instead of the acid in pharmacy as can be seen from Zavitz. It teaches an equivalence of R-NSAIDs and their esters in the treatment of AIDS. Thus in view of the latter it would have been obvious to use esters of the R-NSAIDs taught by the former in the treatment of cancer.

Claims 1-6 and 10-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al, supra in view of Manfredini et al. for essentially the reasons of record with the Wechter et al patent replacing the Wechter literature article.

Claims 1-6 and 10-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavitz in view of Manfredini et al for essentially the reasons of record except that Zavitz teaches the utility of esters of NSAIDs broadly at col. 2.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavitz in view of Alper for essentially the reasons of record.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al, supra in view of Zavitz and Alper for essentially the reasons of record when using the Wechter article.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification doesn't recite the process described in said claim. With ascorbic acid applicants must protect the primary OH group, then protect the vicinal OH groups, then deprotect the primary OH group, then react the primary OH group with an activated form of R-NSAID and then remove said protecting groups. See Ex. 1.

Applicant's arguments filed 2-22-2005 have been fully considered but they are not persuasive. Zavitz includes esters broadly. See par. [0011] and [0012]. Diclofenamic

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acid is arylacetic acid homologous to the instant arylpropionic acids. Tartaric acid is used by Alper et al as an enantiomeric director and not as an esterifying agent.

Because of the switch to the Wechter et al patent this rejection is not made final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

5-27-2005



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